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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/695,145	10/28/2003	Martin Gould	6149	6451

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EXAMINER	
YU, MELANIE J	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 02/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/695,145	GOULD ET AL.	
	Examiner	Art Unit	
	Melanie Yu	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 12, 13, 24 and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 12 and 24 recite the phrase "generally L-shaped", it is unclear what is encompassed by this term and how L-shaped the housing must be in order to be generally L-shaped.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

2. Claims 1-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wickstead et al. (US 6,634,243) in view of Anderson et al. (US 6,267,722).

Wickstead et al. teach a lateral flow immunoassay device comprising: a housing (sample device; col. 4, line 41) including means for holding a test sample collector with a test sample contained within the collector (sample collector; col. 4, lines 41-42); an elongated holder member securing at least one immunoassay test strip therein (test strip container; 50, Fig. 1; col. 4, line 42); a first chamber containing a first, pre-treatment reagent of a buffer (buffer container; col. 4, line 41); a second chamber (filter; col. 4, line 42); means for contacting the test sample with the pre-treatment reagent and allowing the test sample to mix with the first reagent to form a mixture (col. 9, lines 13-17); and means for allowing the mixture to contact at least one immunoassay test strip (col. 5, lines 43-49). Wickstead et al. fail to teach the second chamber containing a second reagent and means for introducing the second reagent to the mixture and allowing the mixture to react with the second reagent for a period of time.

Anderson et al. teach a chamber (filter disposed before the test strip) containing a second reagent (col. 32, line 60-col. 33, line 2); a means for introducing a second reagent to a mixture and allowing a mixture to react with a second reagent for a period of time (col. 14, lines 7-15; col. 32, line 60-33, line 2) and means for allowing the mixture and second reagent combination to contact an immunoassay test strip (col. 33, lines 3-8), in order to provide point of care diagnostic analysis system with rapid and accurate results.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to for the filter in the device of Wickstead et al., being a second chamber containing a second reagent; a means for introducing a second reagent to a mixture and a means for allowing a mixture and second reagent to contact an immunoassay strip as taught by

Anderson et al., in order to enhance the diagnostic and risk assessment capabilities of decision-support methodologies in immunochromatographic assay systems.

Regarding claims 3-5 and 17-19, Anderson et al. teach the second reagent being disposed within a filter being a binder (labeled antibody conjugate; col. 32, line 60-col. 33, line 2) of a colloidal gold-antibody complex (col. 35, lines 22-23) or an antigen (col. 6, lines 53-56).

With respect to claims 6, 7, 10, 11, 15, 20, 22 and 23, Wickstead et al. teach the pretreatment reagent contained within a rupturable enclosure wherein the contacting means include a piercing membrane that ruptures the enclosure and releases the first reagent, and the test sample being in fluid communication with the first reagent when the test sample is released from the sample collector (col. 5, lines 14-26). Wickstead et al. further teach the contacting means including a button (110, Fig. 13) and a piercing member, wherein the button activates the piercing membrane to rupture the enclosure and release the first reagent contained therein (fluid-tight press fit between buffer container and sample collector, Fig. 13; col. 4, line 63-col. 5, line 6). Wickstead et al. also teach the holding means including an elongated slot (261 and 262, Fig. 16).

With respect to claims 8, 9 and 21, Wickstead et al. teach introducing means including apertures in communication with the second chamber through which the mixtures flows (filter, 230, Fig. 16; col. 5, lines 43-67) the mixture would contact the second reagent of Anderson et al. that is disposed within the filter (col. 32, line 60-col. 33, line 2). Wickstead et al. further teach the means for allowing the mixture to contact the at least one immunoassay test strip including the holding member being isolated so that at least one test strip does not contact the mixture until the mixture has reacted with the filter (col. 6, lines 64-65; col. 8, lines 33-36), which would cause

the mixture to react with the second reagent disposed in the filter as taught by Anderson et al. before contacting the test strip (col. 32, line 60-col. 33, line 2).

Regarding claims 12, 13, 24 and 25, Wickstead et al. teach the housing being generally L-shaped (254, Fig. 16) with a vertical leg (lower part of device comprising parts 260, 261, 262) having a top and a bottom end (top end is toward the cap, 210, and bottom end is the lower part of the device in Fig. 16) and a horizontal leg extending outwardly from the bottom of the vertical leg (horizontal leg comprises parts 220 and 210 in Fig. 16 when fully assembled), wherein the test strip (240, Fig. 16) is located within the vertical leg (between 261 and 262 in Fig. 16).

Conclusion

3. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Yu whose telephone number is (571) 272-2933. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Melanie Yu
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Art Unit 1641

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02/16/05